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REMARKS

In the Office Action dated October 11, 2006, the Examiner has set forth a requirement for restriction under 35 U.S.C. §121, alleging that the subject matter defined by the claims of the present invention represents sixty-six (66) separate and distinct groups of inventions. Specifically, the Examiner has divided the claims into two categories:

Category I. Claims 45-55, 59-61, 68-70 and 87-91, which link Groups I-XXX; and
Category II. Claims 74-76 and 86-88, which link Groups XXXI-LXVI.

Generally speaking, the first category relates to methods of causing non-spontaneous and controlled differentiation of an undifferentiated stem cell into a mesodermal cell. The Examiner has divided claims of this category into Groups I-XXX, apparently depending on the stem cell and the cell into which the stem cell differentiates. The second category relates to isolated cell populations, and the Examiner has divided claims of this category into Groups XXXI-LXVI.

In order to be fully responsive to the Examiner's requirement for restriction, Applicant provisionally elects Group VI, claims 56-58, 62-63, 65 and 71, for continued prosecution with the linking claims 45-55, 59-61, 68-70 and 87-91. Group VI is directed to a method of causing non-spontaneous and controlled differentiation of an embryonic stem cell, pluripotent stem cell or a totipotent stem cell wherein the undifferentiated stem cell differentiates into a cardiac muscle cell or cell lineage. Applicant acknowledges that upon the allowance of the linking claims, the restriction requirement applied to the linking claims would be withdrawn.

However, pursuant to 37 C.F.R. §§ 1.111 and 1.143, Applicant hereby traverses the Examiner's requirement for restriction and request reconsideration thereof in view of the following remarks.

An Examiner's authority to require restriction is defined and limited by statute:

If two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions.

35 U.S.C. § 121, first sentence (emphasis added). The implementing regulations of the Patent and Trademark Office include the mandate that restriction is appropriate only in cases presenting inventions which are both independent and distinct, 37 C.F.R. §§1.141-142.

Without a showing of independence and distinctness, a restriction requirement is unauthorized. In the present application, the claims which the Examiner has grouped separately are not "independent and distinct" so as to justify the restriction requirement.

Specifically, the present invention is directed to direct differentiation of the stem cell to a mesoderm cell. The present inventors are the first to be able to control this differentiation process. In particular, the claimed invention provides methods for differentiating the stem cell to a mesoderm cell by using embryonic cells or factors derived from the embryonic cells. In preferred embodiments, an endodermal or ectodermal embryonic cell is used. Most preferred is an endoderm cell. By selecting an endoderm cell, differentiation of a stem cell can be controlled. By employing the conditions identified by the present invention, a differentiated end cell of a desired type, such as a cardiomyocyte, skeletal muscle or endothelial cell, can be obtained.

Therefore, Applicant respectfully submits that at least within the first category, Groups I-XXX are all related to each other and linked together under a single inventive concept, and are therefore not "independent and distinct". Alternatively, Applicant respectfully requests that the Examiner consider examining all claims wherein the undifferentiated stem cell is an embryonic stem cell, pluripotent stem cell or a totipotent stem cell, without limiting to any specific differentiated end cell type.

Applicant respectfully suggests that in view of the continued increase of official fees and the potential limitation of an applicant's financial resources, a practice which arbitrarily imposes restriction requirements may become prohibitive and thereby contravene the constitutional purpose to promote and encourage the progress of science and the useful arts. Moreover, under the regulatory changes as a consequence of the General Agreement on Trade and Tariffs (GATT), applicants are required to conduct simultaneous prosecution, as here, requiring excessive filing costs or to otherwise compromise the term of related patent assets.

It is vital to all applicants that restriction requirements issue only with the proper statutory authorization, because patents issuing on divisional applications which are filed to prosecute claims that the Examiner held to be independent and distinct can be vulnerable to legal challenges alleging double patenting. The third sentence of 35 U.S.C. §121, which states that a patent issuing on a parent application "shall not be used as a reference" against a divisional application or a patent issued thereon, does not provide comfort to applicants against such allegations. The Court of Appeals for the Federal Circuit has declined to hold that § 121 protects a patentee from an allegation of same-invention double patenting, Studiengesellschaft Kohle GmbH v. Northern Petrochemical Co., 784 F.2d 351, 355, 288 U.S.P.Q. 837, 840 (Fed. Cir. 1986). In Gerber Garment Technology Inc. v. Lectra Systems Inc., 916 F.2d 683, 16

U.S.P.Q. 2d 1436 (Fed. Cir. 1990), the court held that §121 does not insulate a patentee from an allegation of "obviousness-type" double patenting, and in fact affirmed the invalidation on double patenting grounds of a patent that had issued from a divisional application filed following a restriction requirement. Furthermore, it is far from clear that the step of filing a terminal disclaimer is available to resolve a double patenting issue that arises after the issuance of a patent on the divisional application.

All these considerations indicate that the imposition of a restriction requirement with inadequate authority can lead to situations in which an applicant's legitimate patent rights are exposed to uncertainty and even extinguished. Accordingly, to protect a patentee's rights and to serve the public interest in the legitimacy of issued patents, Applicant respectfully urges the Examiner not to require restriction in cases such as the present application wherein various aspects in a unitary invention are claimed.

Finally, Applicant respectfully submits that a determination to make the pending restriction requirement final must evidence the patentable distinctness of all defined sixty-six groups, one from another, as presented by the Examiner.

In view of the foregoing comments, it is respectfully urged that the Examiner reconsider and withdraw the requirement for restriction and provide an action on the merits with respect to all the claims.

Respectfully submitted,



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